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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/567,661

09/06/2006

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/567,661 | Applicant(s) LEVER ET AL. | |
| | Examiner MARIA B. MARVICH | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to an amendment filed 11/19/09. Claim 49 is pending.

Claim Objections

Claims 49 and 50 are objected to because of the following informalities: Claim 49 requires a number of minor amendments.

Claim 49 is directed to a method of delivering a therapeutic or antigenic protein or peptide to an individual. However, the claim does not subsequently refer to this protein or peptide. Secondly, the coding sequences should be operably linked to expression control sequences. Thirdly, articles are required prior to "antigenic protein" in line 1, "host cell" and pharmaceutical composition in line 4 and the article "the" prior to "heterologous nucleic acid" in line 7. As well, the recitation "said vector being packaged" does not indicate how this step happens.

Overall, the claim should be amended such,

"A method of delivering a therapeutic or an antigenic protein or peptide to an individual comprising: administering to the individual an effective amount of a chimaeric virus comprising a heterologous nucleic acid sequence encoding the therapeutic or the antigenic protein or peptide under control of an expression control sequences, or a vector system, a host cell, or a pharmaceutical composition ~~comprising said chimaeric virus thereof~~, wherein the chimaeric virus is produced by a method comprising culturing a host cell which comprises one or more Simian Immunodeficiency Virus (SIV) nucleic acid sequences encoding ~~capable of producing~~ an SIV capsid under control of expression control sequences and which further comprises a vector

Art Unit: 1633

comprising a Human Immunodeficiency Virus type 2 (HIV-2) packaging signal and ~~a~~ the heterologous nucleic acid sequence; wherein said culturing results in said vector being packaged in the SIV capsid to produce the chimaeric virus.”

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (US 20060067948; see entire document). **This is a new rejection.**

Allen et al teach methods of making a virus wherein the method utilizes a vector comprising an HIV-2 packaging signal and a heterologous nucleic acid and sequences encoding an SIV envelope (see e.g. ¶ 0050, 0054 and 0059). The heterologous gene encodes a variety of therapeutic proteins or peptides (see e.g. ¶ 0072). The virus is administered to humans for example (see e.g. ¶ 0076).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

Art Unit: 1633

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

/Maria B Marvich/
Primary Examiner, Art Unit 1633